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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/551,809

09/30/2005

Hiroyuki Osada

3749-0106PUS1

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EXAMINER

COOK, LISA V

ART UNIT

PAPER NUMBER

1641

NOTIFICATION DATE

DELIVERY MODE

05/05/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No. 10/551,809	Applicant(s) OSADA ET AL.	
	Examiner LISA V. COOK	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) 8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 9-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-12 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>093005 051806 010307</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicants' election without traverse of Group I (claims 1-7 and 9-12) in the reply filed 4/15/08 is acknowledged.

The Restriction Requirement is deemed proper and is therefore made **FINAL**.

2. Currently, claims 1-12 are subject to Restriction and Election Requirement. Claim 8 has been withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as claims drawn to a non-elected invention. Claims 1-7 and 9-12 are under examination.

Information Disclosure Statement

3. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the examiner on form PTO-892 or applicant on form PTO-1449 have cited the references they have not been considered.

4. The information disclosure statement filed 9/30/05 has been considered as to the merits before First Action.

5. The information disclosure statement filed 5/18/06 has been considered as to the merits before First Action.

6. The information disclosure statement filed 1/3/07 has been considered as to the merits before First Action.

Specification

7. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

8. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The instant abstract includes the legal phraseology "comprising". It should be eliminated in order to obviate this objection.

9. The use of several trademarks has been noted in this application. They should be capitalized wherever they appears and be accompanied by the generic terminology. For example see TWEEN on page 22.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

10. The brief description of the drawing for figure 1 on page 17 does not include the letters (a, b, and c) identified in the figure. Please add (a, b, and c) to the brief description.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 5-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. (Claim 7 is rejected as being dependent of claim 5).

A. Claim 5 recites that the solid support is a *support for* a microarray. This is vague and indefinite because it is not clear if Applicant intends to mean that the support is a microarray or if Applicant intends to mean any support that a microarray can be placed on. This is further vague and indefinite because claim 6 recites that a microarray is produced in claim 5, but only a solid-phase support appears to be produced. As recited the metes and bounds of the claim can not be determined. Appropriate correction is required to eliminate ambiguity. It is suggested that claim 5 merely read "the solid support is a microarray" in order to obviate this rejection.

B. Claim 6 recites the limitation "a produced microarray" in claim 5. There is insufficient antecedent basis for this limitation in the claim. Claim 5 merely reads on a solid-phase support. Appropriate correction is required.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

I. Claims 1-7 are rejected under #5 U.S.C. 102(b) as being anticipated by Fuji Photo Film Co. (JP 2001-178472 Machine/English Translation) as evidenced by Billig et al. (BioTechniques Molecular Laboratory Methods Series, 1998, 2 (Apoptosis Detection and Assay Methods), pages 15-22, Abstract Only).

Fuji Photo Film teach methods of fixing a DNA fragments onto a solid-phase support. This is supported by the specification on page 10 1st paragraph. Fuji Photo Film teaches the immobilization of DNA fragments onto high-density array (DNA chips or microarrays). See section 0001. The solid supports include photoreactive reagents (for example see section 0024-0032). Fuji Photo Film is silent with respect to the DNA fragments being low molecular weight compounds however this is deemed an inherent property of the measured fragments. DNA fragments may encompass low molecular weight compounds as evidenced in the abstract to Billig et al. Therefore it necessarily flows that the DNA fragments of Fuji encompass low molecular weight compounds. A claim is anticipated if each element of the claim is found, either expressly described or under principles of inherency, in a single prior art reference, or that the claimed invention was previously known or embodied in a single prior art device or practice.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

II. Claims 9-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fuji Photo Film Co. (JP 2001-178472 Machine/English Translation) as evidenced by Billig et al. (BioTechniques Molecular Laboratory Methods Series, 1998, 2 (Apoptosis Detection and Assay Methods), pages 15-22, Abstract Only) in view of Chandler et al. (USP# 5,981,180).

Please see previous discussions of Fuji Photo Film Co. (JP 2001-178472 Machine/English Translation) as evidenced by Billig et al. (BioTechniques Molecular Laboratory Methods Series, 1998, 2 (Apoptosis Detection and Assay Methods), pages 15-22, Abstract Only).

Fuji Photo Film Co. (JP 2001-178472 Machine/English Translation) as evidenced by Billig et al. (BioTechniques Molecular Laboratory Methods Series, 1998, 2 (Apoptosis Detection and Assay Methods), pages 15-22, Abstract Only) differ from the instant invention in not specifically teaching low molecular weight immobilization onto beads and the utility of said beads.

However, Chandler et al. disclosed methods for multiplexed diagnosis and genetic analysis of enzyme, DNA fragments, antibodies, and other biomolecules via labeled bead sets by flow cytometry. Abstract. Each bead set is uniform with respect to at least three and preferably four known classification parameters, such as forward light scatter, side light scatter, fluorescent emission, etc. (column 4, lines 4-17)

The classification parameters are measured and used to identify and quantify (concentration) the analyte that the bead is designed to effect. Column 4, lines 43-50. In an assay procedure the beads are mixed with a fluid to be analyzed, a variety of antigens, and a label to permit antigen-antibody interaction. Column 6, lines 9-27.

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It would have been *prima facie* obvious to one of ordinary skill in the art to take the immobilization procedures demonstrated by Fuji Photo Film Co. (JP 2001-178472 Machine/English Translation) as evidenced by Billig et al. (BioTechniques Molecular Laboratory Methods Series, 1998, 2 (Apoptosis Detection and Assay Methods), pages 15-22, Abstract Only) and create bead populations with low molecular weight reagents because Chandler et al. taught bead populations and methods allows for the detection of a plurality of analytes simultaneously during a single flow cytometric process step further increasing the speed of sample processing and reducing the cost to analyze a clinical sample. Column 8, lines 27-31.

The immobilization of reagents onto various solid supports is routine optimization that are almost always determined and used in reagent studies. Unless the result obtained in the instant application is a significant and unexpected difference over the prior art, it would have been prima facie obvious for one of ordinary skill in the art to utilize variations of known solid supports to immobilize and utilize low molecular weight compositions.

14. For reasons aforementioned, no claims are allowed.

Remarks

15. Prior art made of record and not relied upon is considered pertinent to the applicant's disclosure:

Liu (Applied Biochemistry and Biotechnology - Part B Molecular Biotechnology, 2001, Vol.17, No.2, pages 183-185) teach methods on immobilizing DNA fragments onto magnetic beads.

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16. Papers related to this application may be submitted to Group 1600 by facsimile transmission. The Group 1641 – Central Fax number is (571) 273-8300, which is able to receive transmissions 24 hours/day, 7 days/week. In the event Applicant would like to fax an unofficial communication, the Examiner should be contacted for the appropriate Right Fax number.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (571) 272-0816. The examiner can normally be reached on Monday - Friday from 7:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (571) 272-0823.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lisa V. Cook
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4/25/08

/Lisa V. Cook/
Examiner, Art Unit 1641